UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YING DING,
BRIAN HALSALL and WILLIAM R. HEINEMAN

Appeal No. 2006-0703
Application No. 09/268,437

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-5, 11 and 12.[1] Claims 1, 11 and 12 are representative of the claims on appeal, and read as follows:

1. A simultaneous electrochemical assay device comprising a cell adapted to receive a sample, said cell having a surface having a plurality of analyte binding areas, each of said analyte binding areas having a different specific analyte binding substrate; and a plurality of working electrodes adapted to quantitatively measure enzymatic reaction product, each working electrode adjacent to one analyte

[1] Claims 6-9 are also pending, but stand withdrawn from consideration as being drawn to a non-elected invention.

binding area and separated from the nearest adjacent analyte binding area by a distance and a common reference electrode for said plurality of working electrodes wherein said device does not have means to mix a sample in said cell.

11. An electrochemical assay device comprising a cell adapted to receive a sample and simultaneously test multiple different analytes, said cell having a surface having a plurality of analyte binding areas, each of said analyte binding areas having a different specific analyte binding substrate; and a plurality of working electrodes and each working electrode adjacent to one analyte binding area and separated from the nearest adjacent analyte binding area by a distance, all of said binding areas coated with a single quiescent solution containing substrate reactive with enzymes bonded to analyte binding areas wherein said device does not have means to mix a sample in said cell.

12. The assay device claimed in claim 11 wherein said device has a common reference electrode for said plurality of working electrodes.

The examiner relies upon the following references:

Cozzette et al. (Cozzette)	5,063,081	Nov. 5, 1991
Henkens et al. (Henkens)	6,391,558	May 21, 2002

Claims 1-5, 11 and 12 stand rejected under 35 U.S.C. §102(e) as being anticipated by Henkens. In addition, claim 11 stands rejected under 35 U.S.C. §102(b) as being anticipated by Cozzette. After careful review of the record and consideration of the issues before us, we affirm the rejection of claim 11 as to Cozzette. The rejection of claims 1-5 and 12 as being anticipated by Henkens, however, is reversed. Because we affirm the rejection of claim 11 as to Cozzette, we decline to reach the rejection of claim 11 under 35 U.S.C. §102(e) as being anticipated by Henkens.

DISCUSSION

Claim 11 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Cozzette.

Cozzette is relied upon for teaching "a simultaneous electrochemical assay device (amperometric base sensor) fabricated on a substantially planar silicon substrate comprising a unit cell for holding a sample," wherein "[t]he device has a plurality of working (catalytic) electrodes with identical geometry and area, i.e. analyte binding area or biolayer, and enzyme incorporated thereto." Examiner's Answer, page 5. Cozzette is also relied upon for teaching that "[t]he working electrodes on analyte binding areas are overlain and aligned with analyte specific proteins," and for teaching "that a plurality of electrodes may be present in a biosensor for the simultaneous measurement of different analytes using electrochemical assay procedures (see columns 47-51, column 58, lines 38-48, column 25, and Figure 4)." Id. at 5-6.

It is axiomatic that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that Cozzette teaches all of the limitations of claim 11, and the rejection is affirmed.

Appellants contend that the disclosure of Cozzette is primarily drawn to the manufacture of microfabricated sensing devices. See Appeal Brief, page 8. Appellants argue that Cozzette does not "use a single quiescent solution

containing substrate reactive with enzymes bonded to the analyte binding area," thus "it cannot be used in the same manner as applicants' invention." Id. at 9. According to appellants, the assay structure of claim 11 is being claimed during use, and the structures in Figures 3 and 4 "would never be covered with a single quiescent solution containing substrate reactive with enzymes bonded to the analyte binding area." Reply Brief, pages 4-5.

Claim 11 requires a surface having a plurality of analyte binding areas, a plurality of working electrodes, each working electrode adjacent to an analyte binding area and separated from the nearest adjacent analyte binding area by a distance, all of said binding areas coated with a single quiescent solution containing substrate reactive with enzymes bonded to analyte binding areas wherein said device does not have means to mix a sample in said cell.

Cozzette at column 74 teaches a dual analyte combined sensor for glucose and cholesterol. One electrode is coated with a solution containing glucose oxidase, while a second, adjacent, electrode is coated with a solution containing cholesterol oxidase. See id. at Col. 75, lines 1-19. The sensor thus has a plurality (two) of working electrodes, each working electrode adjacent to an analyte binding area (the glucose oxidase and the cholesterol oxidase) and separated from the adjacent binding area by a distance. Once the sensor is exposed to a test sample containing glucose and cholesterol, it reads on all of said binding areas coated with a single quiescent solution containing substrate reactive with enzymes bonded to analyte binding areas wherein said device

does not have means to mix a sample in said cell. Although Cozzette does not explicitly teach the step of covering the sensor with a test sample, the reference does teach the use of the biosensors of the invention, see columns 47-52, and column 73 (assay procedure for analysis of theophylline), and also teaches that glucose oxidase and cholesterol oxidase produce hydrogen peroxide when reacted with their substrates, i.e., glucose and cholesterol, respectively, see column 50, Table II. Thus, the use of the glucose/cholesterol sensor by the addition of a test sample containing substrate, i.e., glucose and cholesterol, is inherently taught by the reference, and thus Cozzette is deemed to anticipate the invention of claim 11.

Claims 1-5 and 12[2] stand rejected under 35 U.S.C. § 102(e) as being anticipated by Henkens.

Henkens is relied upon for teaching a simultaneous electrochemical assay device, wherein "[t]he device comprises a plurality of working electrodes and one or more reference or counter electrodes." Examiner's Answer, page 4. Henkens, according to the examiner, teaches that the device "may optionally include a common (one) reference or counter electrode, or more reference or counter electrodes." Id. The reference is also relied upon for teaching "that whether in an array of working electrodes or a single working electrode, the electrochemical assay device may optionally include a common (one) reference

[2] Claim 11 also stands rejected, but because we affirmed the rejection of that claim as being anticipated by Cozzette, we decline to reach the merits as to the rejection of that claim as to Henkens.

or counter electrode, or more reference or counter electrodes." Id. Henkens is also relied upon for teaching that the plurality of working electrodes quantitatively measure enzymatic reaction product, and as the device does not contain a means to mix the sample in the cell, the examiner contends that Henkens anticipates the claimed invention. See id. at 4-5.

Claim 1 requires "a plurality of working electrodes adapted to quantitatively measure enzymatic reaction product, each working electrode adjacent to one analyte binding area and separated from the nearest adjacent analyte binding area by a distance and a common reference electrode for said plurality of working electrodes wherein said device does not have a means to mix a sample in said cell." That is, claim 1 requires a single, i.e., common reference electrode and a plurality, i.e., more than one, working electrodes. Appellants argue that Henkens does not teach the limitation of claims 1 and 12 of a common reference electrode for a plurality of working electrodes, as Henkens requires separate reference electrodes for each working electrode. See Appeal Brief, pages 7-8. We agree, and the rejection is reversed.[3]

The examiner asserts that

> Appellant's contention is contradictory to the teachings of Henkens [ ]. Specifically, at column 6, lines 33-38, Henkens [ ] teach[es] that the electrochemical assay device "need not comprise a plurality of working and reference electrodes, but may comprise a single working electrode and a single reference electrode." Henkens [ ] proceeds to teach that "whether in an array or a single electrode,

[3] Because we have reversed the rejection of claims 1-5 and 12 over Henkens, and affirmed the rejection of claim 11 over Cozzette, we need not address appellants' arguments that Henkens is not a proper reference under 35 U.S.C. § 102(e).

> the biosensor may optionally include one, i.e. common or more reference (counter) electrodes," as recited in the rejected claims.

Examiner's Answer, page 7.

What Henkens in fact teaches at column 6, lines 33-38, is:

> Alternatively, the biosensor need not comprise a plurality of working and reference electrodes but may comprise a single working electrode and a single reference electrode. Whether in an array or a single working electrode, the biosensor may optionally include one or more counter electrodes.

Thus, what Henkens teaches is that when there is a plurality of working electrodes, there is also a plurality of reference electrodes, but that the invention also encompasses the use of a single working electrode and a single reference electrode. Henkens, however, does not teach the use of a single reference electrode with a plurality of working electrodes.

The examiner is apparently reading the second sentence of the above passage as teaching an array with a plurality of working electrodes and a single reference electrode by reading the term "counter electrode" as being equivalent to a "reference electrode." Henkens teaches, however, at column 14, lines 42-49:

> The electrochemical cell comprises two or more electrodes. One electrode serves as a reference electrode and one is a working electrode. In one embodiment, two electrodes are present, in which case the current flows between the working and reference electrodes. Alternatively, three electrodes are present; a working, a reference and a counter electrode, in which case the current flows between the working and counter electrodes.

The above passage demonstrates that the reference electrode is different from the counter electrode, and the passage at column 6 of the patent cannot be read

as teaching an array comprising a plurality of working electrodes and a single reference electrode.

CONCLUSION

Because the examiner has failed to set forth a prima facie case that claims 1-5 and 12 are anticipated by the Henkins reference, the rejection as to those claims is reversed.

The rejection of claim 11 as being anticipated by Cozzette, however, is affirmed. Since our reasoning with respect to the obviousness rejection differs from that of the examiner, we designate our affirmance of that rejection as a new ground of rejection under 37 CFR § 41.50(b). See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976).

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED-IN-PART; 37 CFR § 41.50(b)

Toni R. Scheiner)
Administrative Patent Judge)
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) BOARD OF PATENT
Eric Grimes)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Lora M. Green)
Administrative Patent Judge)

LMG/jlb

Wood, Herron & Evans, LLP
2700 Carew Tower
441 Vine Street
Cincinnanti, OH 45202